FOR US POSTAL SERVICE DELIVERY: Office for Human Research Protections 6100 Executive Boulevard, Suite 3B01 National Institutes of Health (MSC 7507) Rockville, Maryland 20892-7507 FOR HAND DELIVERY OR EXPRESS MAIL:

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November 27, 2000

James W. Wagner Provost Case Western Reserve University 10900 Euclid Avenue Cleveland. Ohio 44106-7004

Christian LaMantia Compliance Officer Case Western Reserve University 10900 Euclid Avenue Cleveland, Ohio 44106-7015

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M-1521

Dear Dr. Wagner and Ms. LaMantia:

The Office for Human Research Protections (OHRP) has reviewed Ms. LaMantia's letter dated November 10, 2000, responding to allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human subjects involving possible research conducted by investigators at the Weatherhead School of Management on subjects in university computer rooms.

OHRP acknowledges your report that Drs. Richard Boyatzis and Diana Bilimoria of the Department of Organizational Behavior in the Weatherhead School of Management have never conducted any research in university computer rooms.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination

Page 2 of 2 Case Western Reserve University November 27, 2000

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D.

Director, Division of Compliance Oversight

cc: Dr. Terry White, President, MetroHealth System

Dr. Farah M. Walters, President and Chief Executive Officer, University Hospitals of Cleveland

Dr. William D. Montague, Director, Louis Stokes Department of Veterans Affairs Medical Center

Mr. Philip A. Cola, Director, Grants Administration, UHC

Ms. Betty L. Dunger, Coordinator, IRB, MMC

Dr. Joseph Fagan, Chair, IRB-01, CWRU

Dr. John R. Murphy, Chair, IRB-02, UHC

Dr. Thomas R. Vrobel, Chair, IRB-03, MMC

Dr. P. Eric Konicki, Chair, IRB-04, IRB-04, VAMC

Dr. John Mather, Director, Office of Research Compliance and Assurance, Veterans Health Administration

Commissioner, FDA

Dr. David Lepay, FDA

Dr. James F. McCormack, FDA

Dr. Greg Koski, OHRP

Dr. Melody H. Lin, OHRP

Dr. J. Thomas Puglisi, OHRP

Dr. Jeffrey H. Cohen, OHRP

Dr. Katherine Duncan, OHRP

Ms. Roslyn Edson, OHRP

Mr. Barry Bowman, OHRP